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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,224	11/06/2001	Isaac B. Horton III	1300-015	6966

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	PAPER NUMBER
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/008,224	HORTON, ISAAC B.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This final action is in response to the amendment received on 10/27/2006

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-4, 10-14, 17, 26-27, 30, 39, 48, 52 and 61 rejected under 35 U.S.C. 102(e) as being anticipated by Goodrich, Jr. et al (U.S.P.N. 6,258,577) and if necessary as evidenced by "Electromagnetic Spectrum" Internet printout.

Regarding claims 1, 39 and 61, Goodrich discloses a blood purification system (figure 7) and a method for sterilizing microorganisms in blood (col.3, lines 50-55 and col.4, lines 1-4 where killing microorganisms is equivalent to sterilization of microorganisms) including the following: a blood purifier (rectangular structure labeled 194 in figure 7) that produces a UV dose (UV dose is produced within the blood purifier

at the unlabeled connection between 164 and 162) with a housing (figure 7:164) that include an inlet and outlet (unlabeled inlet and outlet in figure 7), providing a UV light source (figure 7:160) connected by an optical connection (figure 7:162) positioned to provide a focused, controllable light output (col.7, lines 66-67, col.8, lines 1-5, col.10, lines 24-30 and col.13, lines 15-18) to the blood purifier (rectangular structure labeled 194 in figure 7), a control mechanism (col.8, lines 8-14), a UV dose zone (unlabeled total inner volume within housing 164) in the housing, which is not a human (col.9, lines 6-10), the dose zone includes a dose region for the effective sterilization of microorganisms in a blood (unlabeled right inner volume part within housing 164 in figure 7), activating the UV light source (example 6) and passing the blood through the housing (figure 7:186, 164 and 188) in order to provide a sterilized blood. In addition, the light source in the system of Goodrich is capable of providing light output between about 250 nm and about 260 nm. Goodrich teaches that wavelengths in the ultraviolet to visible range can be used as well (col.7, lines 20-28). See the "Electromagnetic Spectrum" Internet printout where the ultraviolet range is known to be between 10-400 nm.

Regarding claims 2-4, 10-14, 17, 26-27, 30, 48 and 52, Goodrich teaches the following: the light source includes a UV lamp (figure 7:160), optic (figure 7:162), a housing (figure 7:164), a power supply (a necessary inherent feature in order for the apparatus to function), light source that includes an optical component positioned to provide a focused (col.13, lines 15-18), controllable light output (col.8, lines 1-4), light source is UV transmissive (inherent property of fiber optics to totally transmit light

through internal reflection), light source is UV reflective (inherent property of fiber optics whose internal core is made up of material with high refractive index), light source optical component are reflectors (inherent property of fiber optics whose internal core is made up of material with high refractive index), a fiber optic transmission line (inherent property of fiber optics to totally transmit light through internal reflection), blood purifier (rectangular structure labeled 194 in figure 7) includes a dose zone (unlabeled inner volume within housing 164) and a housing, dose zone includes a delivery device (inactivated blood at the end of the volume within the housing 164 is delivered to line 188), end-emitting fiber optic transmission lines (figure 7:unlabeled end of 162 connected to 164) and the delivery device with a planar configuration (the decontaminated blood product line has an inherent two-dimensions, which are diameter and length).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 5, 8, 18, 28-29, 31, 40, 50-51 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577) as applied to claims 4, 17, 26, 39 and 48 and further in view of Horton et al (U.S.P.N. 6,454,937).

Regarding claims 5, 8, 18, 28-29, 40 and 50-51, Goodrich fails to teach the following: UV lamp is a high-intensity lamp, UV lamp is a mercury halide lamp, housing is UV reflective, delivery device is a vertical riser configuration and the vertical riser configuration system is a scalable to applications. Horton teaches the following: high-intensity lamp (figure 5:62) such as mercury halide lamp (the reference teaches that various types of lamps can be used in the device, col.6, lines 15-20, such that choosing a certain conventional type is a matter of choice of design), the housing is UV reflective (within 50 there is 64 as shown in figures 4-5), the delivery device is a vertical riser configuration (figure 7:200) with intrinsic features, for example, predetermined blood flow rate, the VRC is scalable to applications (the reference teaches various design modification in col.7, lines 25-27, lines 47-49, lines 61-65 and col.5, lines 56-59 such that depends on the characteristics of the water being treated) and the delivery device is a planar configuration (figures 4-5). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Goodrich to substitute the blood purifier with the vertical riser configuration device of Horton since the VRC creates turbulence at the top of the column that result in having the microorganisms being more effectively radiated by the UV light beam as disclosed by Horton (col.8, lines 5-7).

Regarding claims 31 and 53, the Goodrich reference teaches that the blood purifier, which includes a housing is made up from quartz (col.8, lines 45-47).

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577) as applied to claim 4 and further in view of Windham et al (U.S.P.N. 6,587,575).

Goodrich fails to teach the use of a spectral calibration lamp, however, Windham teaches the use of spectral calibration lamps (col.15, lines 33-35). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the UV lamp of Goodrich with the spectral calibration lamp since such spectral lamps are capable of having a precise distinct wavelength peaks (Windham, col.15, lines 40-44).

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577) as applied to claim 4 and further in view of Danilychev (U.S.P.N. 5,931,557).

Goodrich fails to teach the use of an electrodeless lamp, however, Danilychev teaches using electrodeless lamp (col.20, lines 33-34) and using aluminum or stainless steel as the reflective material (col.3, lines 24-28). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the UV lamp of Goodrich with an electrodeless lamp since such a lamp is known to provide high energy efficient source of Ultraviolet radiation in sterilization applications (col.1, lines 13-20).

9. Claims 9, 15-16, 19-25, 33, 35-38, 41-47, 49, 55 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577) as applied to claims 4, 14, 1, 17, 39, 48 and further in view of DiStefano (Pub. No. US2003/0045868 A1).

Regarding claims 16, 24-25 and 46-47, Goodrich fails to teach a specific type of fiber optic transmission line and that the blood purifier uses enhanced two or three-dimensional design; however, DiStefano teaches a fiber optic transmission line (54 that include glass lines) is removably connectable to light source and the blood purifier (figure 4 includes two nuts where the first 56 and the second is unlabeled that connect 54 to both the light source and the blood purifier) and that the blood purifier uses enhanced two or three dimensional design (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections such that two and three dimensional designs are inherent features of the optic fibers line). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Goodrich by using combined UV light with visible light as taught by DiStefano in order to kill bacteria, virus, fungi, molds and other unclassified pathogens present in blood (paragraph 0003 and 0018).

Regarding claims 33, 35, 41-42, 55 and 57-58, Goodrich fails to teach the following: interior surface of the blood purifier is a UV reflective surface, interior of the blood purifier includes one interior optical component that is attached to the interior surfaces, a portal for removable connection to a fiber optic transmission line, portal optical component positioned between the portal and the interior of the blood purifier

and interior optical component is UV transmissive. DiStefano teaches the following: interior surface of the blood purifier is a UV reflective surface (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections), light source optical component that is UV transmissive (54 such that bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections), fiber optic transmission line (54 that include glass lines) is removably connectable to light source and the blood purifier (figure 4 includes two nuts where the first 56 and the second is unlabeled that connect 54 to both the light source and the blood purifier), dose zone includes a portal (56) for removable connection to fiber optic transmission line (54), portal optical component positioned between the portal opening and the interior of the blood purifier (the fiber optic 54 contains glasses that reflect UV light within the bundle sheath such that any glass within 54 is a portal optical component positioned between the portal opening an the interior of the blood purifier 32), portal optical component is UV reflective that is made up of reflectors (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections), blood purifier includes one interior optical component that is attached to the interior surfaces (the interior surfaces of 32 inherently include optical components made of glass that are attached to such surfaces) and the reflective interior optical components are both UV transmissive and reflective (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

apparatus of Goodrich By using combined UV light with visible light as taught by DiStefano in order to kill bacteria, virus, fungi, molds and other unclassified pathogens present in blood (paragraph 0003 and 0018).

Regarding claims 9, 15, 19-23 and 43-45, Goodrich fails to teach the following: UV lamp emits UVC wavelengths, the fiber optic transmission line is removably connectable to the light source and the blood purifier, the dose zone includes a portal for removable connection to a fiber optic transmission line, portal optical component positioned between the portal opening and the interior of the blood purifier, portal optical component is UV transmissive, portal optical component is UV reflective and types of portal optical components. DiStefano teaches the following: a UV lamp that emits light in the UVV and UVC wavelengths (52 and paragraph 0016), light source optical component that is UV transmissive and UV reflective (54 such that bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections), fiber optic transmission line (54 that include glass lines) is removably connectable to light source and the blood purifier (figure 4 includes two nuts where the first 56 and the second is unlabeled that connect 54 to both the light source and the blood purifier), dose zone includes a portal (56) for removable connection to fiber optic transmission line (54), portal optical component positioned between the portal opening and the interior of the blood purifier (the fiber optic 54 contains glasses that reflect UV light within the bundle sheath such that any glass within 54 is a portal optical component positioned between the portal opening an the interior of the blood purifier 32), portal optical component is both UV transmissive and reflective that is made up of

reflectors (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections) and the interior optical components are both UV transmissive and reflective (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Goodrich by using combined UV light with visible light as taught by DiStefano in order to kill bacteria, virus, fungi, molds and other unclassified pathogens present in blood (paragraph 0003 and 0018).

Regarding claims 36-38, 49 and 59-60, Goodrich teaches the following: interior optical component is UV transmissive (intrinsic property of fiber optics to totally transmit light through internal reflection), interior optical component is UV reflective (intrinsic property of fiber optics whose internal core is made up of material with high refractive index), interior optical components are reflectors (intrinsic property of fiber optics whose internal core is made up of material with high refractive index) and the delivery device (inactivated blood at the end of the volume within the housing 164 is delivered to line 188) includes an end-emitting fiber optic transmission line (figure 7:unlabeled end of 162 connected to 164).

10. Claims 32 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577) in view of Horton et al (U.S.P.N. 6,454,937) as applied to claims 28 and 50 and further in view of Goss (U.S.P.N. 4,705,498).

Regarding claims 32 and 54, both Goodrich and Horton fail to teach the concept of a disposable blood purifier. Figure 1, 20 in the instant application shows the blood purifier as the treatment chamber. Goss teaches the concept of having a disposable irradiation chambers (col.1, lines 15-17). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Goodrich to include a disposable blood purifier as taught by Goss in order to maintain sterility of the procedure (col.10, lines 40-44 and lines 57-62).

11. Claims 34 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577) in view of DiStefano (Pub. No. US2003/0045868 A1) as applied to claims 33 and 55 and further in view of Danilychev (U.S.P.N. 5,931,557).

Regarding claims 34 and 56, both Goodrich and DiStefano fail to teach using aluminum or stainless steel as the reflective material. Danilychev teaches using aluminum or stainless steel as the reflective material (col.3, lines 24-28). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Goodrich to include aluminum since aluminum is used as a reflective material as evidenced by Danilychev (col.3, lines 24-26).

Response to Arguments

12. Applicant's arguments filed on 10/27/2006 have been fully considered but they are not persuasive.

On page 11 of the Remarks section, Applicant argues that the 102 rejection is improper since examiner is relying on Goodrich and the Internet printout

"Electromagnetic Spectrum". The examiner disagrees. First the examiner realizes that the heading of the 102 rejection should have included "as evidenced by" instead of "in view". Second, the Internet printout publication is used to show an inherent property of Goodrich. Goodrich inherently provides UV radiation having wavelength in the range of 250 to 260 nm. Therefore, it is a proper 102 rejection.

On page 11 of the Remarks section, Applicant argues that Goodrich fails to describe a UV dose zone for effectively sterilizing microorganisms in the blood. The examiner disagrees. The disclosure of the instant application teaches on pages 5, 11 and 13 that the UV dose zone is a volume positioned between the UV emitting source and the volume being irradiated. Therefore, Goodrich UV dose zone is the unlabeled total inner volume within housing 164 that falls within the UV emission source, which is being the unlabeled connection between 162 and 164 in figure 7 where inactivation of contaminated blood occurs (Goodrich, col.12, lines 55-67 and col.13, lines 1-12).

On page 12 of the Remarks section, Applicant argues that the UV dose zone optionally include a dose delivery device. The examiner disagrees and refers Applicant to page 4 of action dated 03/02/2006 that the dose delivery device is an end-emitting fiber optic transmission lines (figure 7:unlabeled end of 162 connected to 164).

On page 12 of the Remarks section, Applicant argues that," the prior art does not provide for reflective and/or other optical components as claimed and described by the present invention for creating the effective dosage zone for the sterilization of microorganisms in the blood." The examiner disagrees. Goodrich teaches the optical components being as shown in col.7, lines 66-67, col.8, lines 1-5, col.10, lines 24-30

and col.13, lines 15-18 and also enhances the UV radiation by placing a reflective surface adjacent to the decontamination cuvette (col.13, lines 1-6) such that the combination of UV and reflective surface inherently result in providing an effective dosage zone for the sterilization of microorganisms in blood as recited in the instant claims.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MRC

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER